

Applicants: Janaswamy Madhusudana Rao, et al.
Serial No.: 10/695,471
Filed: October 28, 2003
Page 2

Restriction Requirement Under 35 U.S.C. §121

In the March 19, 2008 Office Action the Examiner required election of one of the two following allegedly patentable distinct inventions:

- I. Claims 1-4 and 6-12, drawn to a herbal composition for the treatment of gastric ulcer, said composition comprising powdered plant parts selected from the group consisting of *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum*, *Trachyspermum roxburghianum*, *Cyclea peltata*, *Embelia ribes*, *Coriandrum sativum*, *Ferula asafetida*, *Aloe barbadensis* and *Evolvulus alsinoides* and one or more pharmaceutically acceptable additives or carriers wherein said composition comprises each of *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum* in about equal proportions by weight and such about equal proportion has a value greater than zero, classified in class 424, subclass 744 or 757 or 725; and
- II. Claim 5, drawn to a composition comprising 5-13 wt. % of powdered plant parts of *Asparagus racemosus*, 5-12 wt. % of powdered plant parts of *Glycyrrhiza glabra*, 8-14 wt. % of powdered plant parts of *Sesamum indicum*, 7-14 wt. % of powdered plant parts of *Musa sapientum*, 4-12 wt. % of powdered plant parts of *Trachyspermum roxburghianum*, 6-12 wt. % of powdered plant parts of *Aloe barbadensis*, 5-12 wt. % of powdered plant parts of *Evolvulus alsinoides*, 6-13 wt. % of powdered plant parts of *Cyclea peltata*, 9-14 wt. % of powdered plant parts of *Embelia ribes*, 7-14 wt. % of powdered plant parts of *Coriandrum sativu* and 8-13 wt. % of powdered plant parts of *Ferula asafetida*, and one or more pharmaceutically acceptable additives or carriers, classified in class 424, subclass 744 or 757 or 725.

The Examiner indicated that if applicants elect Group I or II, applicants are required under 35 U.S.C. §121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held

Applicants: Janaswamy Madhusudana Rao, et al.
Serial No.: 10/695,471
Filed: October 28, 2003
Page 3

allowable. The Examiner stated that, in other words, if applicants elect Group I, applicants are required to distinctly and clearly enumerate and name the optional powdered plants comprising the claim-designated composition of claim 1. However, the Examiner also indicates that upon allowance of a generic claim, applicants will be entitled to consideration of claims to additional species which are written in dependent form or other wise include all the limitations of an allowed generic claim as provided by 37 C.F.R. §1.141. The Examiner further indicated that currently, claims 6, 7 and 9-12 are generic.

In response, applicants elect with traverse, Examiner's Group I, i.e. claims 1-4 and 6-12 drawn to a herbal composition for the treatment of gastric ulcer. Applicants also elect, with traverse, *Cyclea peltata* as the single disclosed species for prosecution at this time.

On page 3-4 of the March 19, 2008 Office Action, the Examiner alleged that the inventions are distinct, each from the other because of the following reasons:

The Examiner alleged that the inventions of Groups I and II are related as combination and subcombination. The Examiner states that the inventions can be shown to be distinct if either or both of the following can be shown: (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability; and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). The Examiner alleged that in the instant case, the combination does not require the particulars of the

Applicants: Janaswamy Madhusudana Rao, et al.
Serial No.: 10/695,471
Filed: October 28, 2003
Page 4

subcombination as claimed for patentability because the combination, due to the presence of additional ingredients, would be patentable even if the subcombination was known and non-obvious, assuming that the prior art does not teach or suggest the presence of the additional ingredients recited in the combination claims. The Examiner also alleged that the subcombination has separate utility by itself in other combinations, as evidenced by the claims themselves.

The Examiner therefore concluded that restriction for examination purposes is proper because these inventions are independent and distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply: (1) the inventions have acquired a separate status in the art in view of their different classification; (2) the inventions have acquired a separate status in the art due to their recognized divergent subject matter; (3) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries); (4) the prior art to one invention would not likely be applicable to another invention; and (5) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant notes that 35 U.S.C. §121 states, in part, that "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require application to be restricted to one of the inventions." [Emphasis added]. Applicant requests that the restriction

Applicants: Janaswamy Madhusudana Rao, et al.
Serial No.: 10/695,471
Filed: October 28, 2003
Page 5

requirement be withdrawn in view of the fact that the claims of Groups I-II are not independent.

Under M.P.E.P. §802.1, "independent" means "there is no disclosed relationship between the subjects disclosed, that is, they are unconnected in design, operation, and effect...". The claims of Groups I-II are related in that claims 1-12 thereof are all drawn to herbal compositions comprising powdered plant parts.

Applicant therefore respectfully asserts that two or more independent and distinct inventions have not been claimed in the subject application because the groups are not independent under M.P.E.P. §802.01. Therefore, restriction is improper under 35 U.S.C. §121.

Additionally, applicant points out that under M.P.E.P. §803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden. There are two criteria for a proper requirement for restriction, namely (1) the invention must be independent and distinct; AND (2) there must be a serious burden on the Examiner if restriction is not required.

Applicant maintains that there would not be a serious burden on the Examiner if restriction were not required. A search of prior art with regard to any of Groups I-II would identify art for the other Group. Moreover, as shown by the same classification in class and subclass (class 424 and subclass 744 or 757 or 725, respectively) the inventions cannot be said

Applicants: Janaswamy Madhusudana Rao, et al.
Serial No.: 10/695,471
Filed: October 28, 2003
Page 6

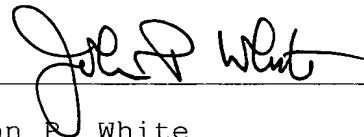
to "have acquired a separate status in the art in view of their different classification." Since there is no serious burden on the Examiner to examine Groups I-II in the subject application, the Examiner should examine Groups I-II together.

Accordingly, applicant respectfully requests that the Examiner reconsider and withdraw the restriction requirement and examine the pending claims on the merits.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee, other than the \$460.00 extension fee, is deemed necessary in connection with the filing of this Communication. However, if any other fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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John P. White Reg. No. 28,678	Date